Risk Factors Comparison 2024-02-29 to 2023-03-20 Form: 10-K

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You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10- K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business. Summary of Risk Factors Investing in our common stock involves significant risks. You should carefully consider the risks described below before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face. • We ~~have a limited operating history~~ **are substantially dependent on the success of SLK** , ~~have not completed any~~ **and our ongoing and anticipated** clinical trials **of SLK** ~~, and have no products approved for commercial sale. • We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and~~ may not be **successful** ~~able to achieve or sustain profitability in the future. We have not generated any revenue from SLK and may never generate revenue or become profitable. • If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our development programs or future commercialization efforts, which would have a negative impact on our business, prospects, operating results, and financial condition~~ . • Our business relies on certain licensing rights from MHKDG **and RCT** that can be terminated in certain circumstances. If we breach ~~the~~ **those** ~~agreement~~ **agreements** , or if we are unable to satisfy our diligence obligations under which we license rights to SLK from MHKDG, we could lose the ability to develop and commercialize SLK **. • We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from SLK and may never generate revenue or become profitable. • We have a limited operating history and have no products approved for commercial sale** . • We have never successfully completed the regulatory approval process for any of our product candidates and we may be unable to do so for any product candidates we acquire or develop ~~. • We are substantially dependent on the success of SLK, and our ongoing and anticipated clinical trials of SLK may not be successful. • We may find it difficult to enroll patients in our clinical trials. If we experience delays or difficulties in the enrolment of patients in clinical trials, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented~~ . • The results of preclinical testing and early clinical trials may not be predictive of the success of our later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or other comparable foreign regulatory authorities. • Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. • Preliminary, interim data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures. • ~~Public health crises such as pandemics~~ **We may find it difficult to enroll patients in** ~~or~~ **our** ~~similar outbreaks could affect our preclinical studies, ongoing and anticipated~~ clinical trials ~~, business, financial condition, and results~~ **. If we experience delays or difficulties in the enrollment** of ~~operations~~ **patients in clinical trials, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented** . • We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do. • SLK may have a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit its commercial potential **. • If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our development programs or future commercialization efforts, which would have a negative impact on our business, prospects, operating results, and financial condition** . • We currently rely on third parties to produce and process SLK. Our business could be adversely affected if the third- party manufacturers fail to provide us with sufficient quantities of SLK or fail to do so at acceptable quality levels or prices. • Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage. MOONLAKE IMMUNOTHERAPEUTICSFORM 10- K FOR THE YEAR ENDED DECEMBER 31, ~~2022PART~~ **2023PART** I Risks Related to Our Limited Operating History, Business, Financial Condition, and Results of Operations We are a clinical- stage company with limited operating history. To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including establishing our business model and key third- party relationships with payers, completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, selling those products for which we may obtain marketing approval and satisfying any post- marketing requirements. We have no products approved for commercial sale and, since our inception, we have been incurring significant operating losses, and expect to incur significant losses in the foreseeable future. As ~~a company, we have not yet completed any clinical trials, including global late- stage clinical trials. In particular, prior to our in- license of SLK on April 29, 2021, (i) MHKDG conducted two Phase 1 trials for SLK, and (ii) Avillion, under a 2017 co- development agreement with MHKDG, conducted a Phase 2b trial for SLK. As~~ with any clinical development, we cannot be certain that our planned clinical trials will begin or be completed on time or at all. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful

product commercialization. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to: • successfully complete our ongoing and planned preclinical and clinical studies for SLK; • timely file and gain acceptance of **IND** ~~investigational new drug~~ applications for our programs in order to commence planned clinical trials or future clinical trials; • successfully enroll subjects in, and complete, our ongoing and planned clinical trials; • obtain data related to SLK and generated prior to the License Agreement, but not ~~yet~~ transferred from MHKDG, which may delay our development and commercialization; • initiate and successfully complete all safety and efficacy studies required to obtain U. S. and foreign regulatory approval for our product candidates, and additional clinical trials or other studies beyond those planned to support the approval and commercialization of SLK; • successfully demonstrate to the satisfaction of the FDA, EMA, or similar foreign regulatory authorities the safety and efficacy and acceptable risk to benefit profile of SLK or any future SLK product candidates; • successfully manage the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any; • obtain the timely receipt of necessary marketing approvals from the FDA, EMA and similar foreign regulatory authorities; • establish commercial manufacturing capabilities or make arrangements with third- party manufacturers for clinical supply and commercial manufacturing; • obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates; • launch commercial sales of our products, if and when approved, whether alone or in collaboration with others; • obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third- party payers; • position our product conducts to effectively compete with other therapies; • obtain and maintain healthcare coverage and adequate reimbursement for our products; • enforce and defend intellectual property rights and claims; and • maintain a continued acceptable safety profile of SLK following approval. Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We may never succeed in these activities and, even if we succeed in commercializing SLK, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable could decrease the value of our shares and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Further, we may encounter unexpected expenses, challenges and complications from known and unknown factors ~~such as the COVID- 19 pandemic~~ . Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date, and we continue to incur research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval from the FDA, EMA and similar foreign regulatory authorities of, and then successfully commercialize, SLK in one or more indications. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of SLK, we may be unable to continue operations without additional funding. We have incurred net losses in each period since we commenced operations on March 10, 2021. Our net losses were $ ~~64~~ **44** . ~~5~~ **1** million for the year ended December 31, ~~2022~~ **2023** . We expect to continue to incur significant losses for the foreseeable future. Our failure to become profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and / or continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our development programs or future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. Developing biopharmaceutical products is a very long, time- consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval from the FDA, EMA, and similar foreign regulatory authorities for, SLK. Even if SLK is approved for commercial sale, we anticipate incurring costs associated with sales, marketing, manufacturing and distribution activities to launch SLK. Our expenses could increase beyond expectations if we are required by the FDA, EMA, or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of SLK. Our future capital requirements depend on many factors, including factors that are not within our control. Based on our current operating plan, we believe our existing cash, cash equivalents and short- term marketable securities, will be sufficient to fund our operations ~~into~~ **to** the **end** ~~second half~~ of ~~2024~~ **2026** . This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our shareholders or the failure to obtain such financing may restrict our operating activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti- dilution protections that adversely affect your rights as a shareholder. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to SLK, or grant licenses

on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide ~~resulting from the ongoing COVID- 19 pandemic~~ . If our costs, in particular costs related to clinical development, manufacture and supply, were to become subject to significant inflationary pressures, it may adversely impact our business, operating results and financial condition. Our failure to raise capital as and when needed or on acceptable terms has in the past had, and in the future may have, a negative impact on our financial condition and our ability to pursue our business strategy, and we have in the past had to, and in the future may have to, delay, reduce the scope of, suspend or eliminate one or more of our research- stage programs, clinical trials or future commercialization efforts ~~. We delayed some of our research- stage programs and clinical trials and incurred additional debt to fund our operations as a result of a longer- than- expected period between the signing and closing of the Business Combination Agreement, dated October 4, 2021 (the " Business Combination Agreement "), by and among Helix, MoonLake AG, the existing equity holders of MoonLake AG set forth on the signature pages to the Business Combination Agreement and the equityholders of MoonLake AG that executed joinders to the Business Combination Agreement (collectively, the " ML Parties "), Helix Holdings LLC, a Cayman Islands limited liability company and the sponsor of Helix, and the representative of the ML Parties (such transactions contemplated by the Business Combination Agreement, collectively, the " Business Combination "). In addition, at this time, we are no longer initially pursuing a clinical trial in axSpA due to redemptions at the time of consummation of the Business Combination~~ . In our own required quarterly assessments, we may conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. Our ability to continue to develop and commercialize SLK is dependent on the use of certain intellectual property that is licensed to us by MHKDG **and RCT** . These licenses are granted pursuant to agreements setting forth certain terms and condition for maintaining such licenses. In the event that the terms and conditions are not met, the licenses are at risk of being revoked and the granting process may be terminated. Our primary license agreement is the License Agreement. See " Business — The Merck Healthcare KGaA (Darmstadt, Germany) License Agreement ". On April 29, 2021, we entered into the License Agreement, a worldwide exclusive license agreement with MHKDG, for certain intellectual property covering SLK and to sublicense certain rights licensed to MHKDG to (i) develop and commercialize products containing SLK; and (ii) manufacture SLK using the underlying yeast strain Pichia pastoris. If there is any dispute between us and MHKDG regarding our rights under the License Agreement, including if we disagree with MHKDG' s comments to our development plan for SLK or if we are unable to make our milestone obligations, our ability to develop and commercialize SLK may be adversely affected. Any uncured, material breach by us under the License Agreement could result in our loss of exclusive rights to SLK and may lead to a complete termination of our product development efforts for SLK. We also have diligence obligations under the License Agreement, including: (a) developing one licensed product in at least two indications; (b) launching and commercializing one product in seven major markets, including with pricing approval if required for commercialization, within 12 months of receiving regulatory approval in the respective market; (c) securing within six months of the effective date of the exclusive license a contract research facility; and (d) initiating two Phase 2 clinical trials for a product within 12 months of the effective date of the exclusive license, taking into account any regulatory requirements from the FDA, EMA or other regulatory authorities, of which we satisfied upon the initiation of our MIRA and ARGO trials. We have not yet demonstrated our ability to ~~successfully complete clinical trials,~~ obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Due to the uncertainties and risks associated with these activities, we may not be successful in meeting these diligence obligations within the required timeframes, and may lose the ability to develop and commercialize SLK **. On May 12, 2023, we entered into an agreement with RCT and MHKDG, effective as of June 1, 2023, pursuant to which we were granted a royalty- bearing, nonexclusive, sublicensable right and license under RCT' s patents and know- how related to a manufacturing process using an underlying yeast strain, Pichia pastoris, to develop, manufacture, use, sell, offer for sale, and import and otherwise commercialize SLK on a world- wide basis, subject to certain restrictions. This agreement replaces our sublicense for similar rights under the License Agreement with MHKDG** . Due to the significant resources required for the development of SLK, we must prioritize the pursuit of treatments for certain indications. We may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success. We are developing therapies for patients with inflammatory skin and joint diseases with unmet needs. In particular, we are developing a portfolio of therapeutic indications for SLK, and are initially focused on the development of SLK in inflammatory diseases including HS and PSA. In May 2022, we initiated our MIRA trial, and in December 2022, we initiated our ARGO trial. ~~We completed patient enrollment for~~ **In October 2023, we announced full 24- week data from** the **global Phase 2** MIRA **clinical** trial ~~in February~~ **. In November** ~~2022~~ **2023** ~~and~~ **,** we **announced top** ~~expect a primary endpoint readout in mid- 2023. The~~ **line 12- week data from the global Phase 2** ARGO trial ~~has received FDA clearance and IRB approval, and continues to meet recruitment targets~~ . Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of any viable commercial product and may divert resources away from opportunities for other indications that later prove to have greater commercial potential or a greater likelihood of success. The primary endpoints for the Phase 2 trials for the therapeutic indications of HS and PsA ~~are~~ **were** the therapeutic scores of the HiSCR and ACR, respectively. **The** ~~Even if the~~ primary endpoints of such trials ~~are~~ **were** met and SLK ~~demonstrates~~ **demonstrated** meaningful increases in such therapeutic scores **. However** , there is no guarantee that ~~such increases~~ **the results will be replicated in Phase 3 studies, nor that they** will lead to ~~the~~ market acceptance or commercial success of SLK, if

approved. Even if SLK receives marketing approval, it may not achieve commercial success. If we do not accurately evaluate the commercial potential or target market for SLK, we may relinquish valuable rights to SLK through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We may make incorrect determinations regarding the viability or market potential of SLK or misread trends in our industry. We may be required to take write- downs or write- offs, restructuring and impairment or other charges that could have a significant negative effect on our financial condition, results of operations and stock price, which could cause you to lose some or all of your investment. We may be required to later write- down or write- off assets, restructure our operations, or incur impairment or other charges that could result in losses. Even though these charges may be non- cash items and not have an immediate impact on our liquidity, the fact that we report charges of this nature could contribute to negative market perceptions about us or our securities. In addition, charges of this nature may cause us to violate net worth or other covenants to which we may be subject. Accordingly, any shareholders could suffer a reduction in the value of their shares. Such shareholders are unlikely to have a remedy for such reduction in value unless they are able to successfully claim that the reduction was due to the breach by our officers or directors of a duty of care or other fiduciary duty owed to them. The only principal assets of our Company are cash and our interest in MoonLake AG, and accordingly we will depend on distributions from MoonLake AG to pay taxes and expenses. We are a holding company and have no material assets other than cash and our ownership of Class V shares in MoonLake AG and common shares in MoonLake AG (" MoonLake AG Common Shares "). As such, we have no independent means of generating revenue or cash flow, and our ability to pay taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the financial results and cash flows of MoonLake AG and its subsidiaries, and distributions we receive from MoonLake AG. There can be no assurance that MoonLake AG and its subsidiaries will generate sufficient profits and / or cash flow to distribute funds to us, or that applicable laws and contractual restrictions, including negative covenants in any debt agreements of MoonLake AG or its subsidiaries, will permit such distributions. Distributions by MoonLake AG to the Company are subject to a Swiss federal dividend withholding tax at the statutory rate of 35 %, unless and to the extent that such distributions constitute a repayment of duly reported capital contributions. Under the current structure, we are not entitled to any relief from Swiss federal dividend withholding tax, such that MoonLake AG will be required to deduct the Swiss federal dividend withholding tax at the statutory rate of 35 % and that such tax deduction will result in a final tax burden for the Company. If our place of management is relocated to Switzerland such withholding tax on distributions from MoonLake AG to us may be eliminated (although such relocation would result in Swiss withholding taxes applying on distributions from us to our shareholders; depending on the specific shareholder, such shareholder may be entitled to a full or partial relief or credit for such Swiss withholding tax). There can be no assurances that our place of management will be relocated or that such withholding tax will be reduced or eliminated. Risks Related to Product Development We have not yet demonstrated our ability to successfully ~~complete clinical trials,~~ obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. If we are required to conduct additional preclinical studies or clinical trials of SLK beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of SLK or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining regulatory approval from the FDA, EMA or other regulatory authorities for our product candidates; • not obtain regulatory approval at all and lose our right and ability under our license from MHKDG to further develop and commercialize SLK; • obtain regulatory approval for indications or patient populations that are not as broad as intended or desired; • continue to be subject to post- marketing testing requirements from the FDA, EMA or other regulatory authorities; or • experience having the product removed from the market after obtaining regulatory approval. Our future success is substantially dependent on our ability to successfully develop SLK for future marketing approval, and then successful commercialization. We are investing a majority of our efforts and financial resources into the research and development of SLK. ~~For our~~ **In October 2023, we announced full 24- week data from the global Phase 2** MIRA **clinical** trial **. In November** ~~, we completed patient enrollment in February 2022~~ **2023** ~~and ,~~ we **announced top** ~~expect a primary endpoint readout in mid- 2023. In late 2022, we initiated our~~ **line 12- week data from the global Phase 2** ARGO trial ~~. The ARGO trial has received FDA clearance and IRB approval, and continues to meet recruitment targets~~ . SLK will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote SLK before we receive marketing approval from the FDA, EMA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. The success of SLK will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any third parties with whom we choose to collaborate in the future. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of SLK, even if approved. If we are not successful in commercializing SLK, or are significantly delayed in doing so, our business will be materially harmed ~~. We may find it difficult to enroll patients in our clinical trials. If we experience delays or difficulties in the enrollment of patients in clinical trials, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented~~ . We may not be able to initiate or continue clinical trials for SLK if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Patient enrollment may be affected by various factors, including if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as SLK, and patients instead enroll in such clinical trials. Our inability to enroll a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether ~~. In addition, disruptions caused by the COVID- 19 pandemic may increase the likelihood that we encounter such difficulties or~~

~~delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials~~ . We will be required to demonstrate with substantial evidence through well- controlled clinical trials that SLK is safe and ~~effective~~ **efficacious** before we can seek marketing approvals for commercial sale. Demonstrations of efficacy or an acceptable safety profile in prior preclinical studies of SLK does not mean that future clinical trials will yield the same results. For instance, we do not know whether SLK will perform in future clinical trials as SLK has performed in preclinical studies and ~~early~~ **prior** clinical trials conducted by us, MHKDG, Avillion ~~LLP~~ or Ablynx. SLK may fail to demonstrate in later- stage clinical trials sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later- stage trials until we have demonstrated satisfactory safety or efficacy results in preclinical studies or earlier- stage trials, which could prevent us from conducting the clinical trials we currently anticipate. There is no guarantee that the FDA, EMA, and other comparable foreign regulatory authorities will consider the data obtained from prior SLK trials sufficient to allow us to ~~continue~~ **initiate** our ~~MIRA~~ **planned clinical** ~~trial~~ **trials** ~~or ARGO trial~~ within the timelines we anticipate, or at all. Even if we are able to initiate our planned clinical trials on schedule, there is no guarantee that we will be able to complete such trials on the timelines we anticipate or that such trials will produce positive results. Any limitation on our ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population that can be treated by SLK, if approved. Before obtaining marketing approval from regulatory authorities for commercialization of SLK, we must complete clinical trials to demonstrate the safety and efficacy of SLK in humans and in selected diseases. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage. The outcome of preclinical studies and **prior** ~~early- stage~~ clinical trials may not be predictive of the success of later clinical trials, and the outcome of preclinical studies and **prior** ~~early- stage~~ clinical trials for a product candidate for a particular indication may not be predictive of the success of preclinical studies and ~~early- stage~~ clinical trials for the same product candidate for a different indication. In particular, in ~~May~~ **October** ~~2022~~ **2023** , we ~~initiated our~~ **announced full 24- week data from the global Phase 2** MIRA **clinical** trial ~~,~~ and **,** in ~~December~~ **November** ~~2022~~ **2023** , we ~~initiated our~~ **announced top- line 12- week data from the global Phase 2** ARGO trial. **We expect** ~~These trials assess therapeutic indication- specific scores and primary endpoints are HiSCR75 (for the MIRA trial in HS) and ACR50 (for the ARGO trial in PsA). As part of the secondary endpoint sets, we measure different score levels, as well as alternative scores and quality- of- life measurements~~ to **commence** ~~build clinical profiles. If the MIRA trial and ARGO trial are successful, we could potentially conduct~~ Phase 3 **clinical trials in HS and PsA in 2024. Although data from the Phase 2 MIRA and ARGO clinical** trials for SLK ~~for each of the two indications,~~ **in patients established SLK as a highly promising and differentiated therapeutic solution in** HS and PsA, **respectively,** ~~as well as in PsO. This is likely to require additional funding. Although data from the~~ Phase **3** ~~2 trial for SLK in patients with PsO conducted by Avillion LLP, under a 2017 co- development agreement with MHKDG, showed a significant improvement in the primary endpoint as compared with placebo, was well- tolerated, and numerically outperformed the group treated with the current standard of care, secukinumab,~~ trials of the efficacy of SLK in patients with HS and PsA may not yield similar results. If a Phase 3 study is initially conducted for SLK in patients with PsA and HS, or PSO, the outcome may be different than ~~the~~ **those observed in the respective** Phase 2 trials. Unexpectedly favorable results of **comparator arms** ~~the standard of care~~ in any ~~Phase 2 or Phase 3~~ trial could lead to unfavorable comparisons to SLK. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA, EMA, or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective contract research organizations (“ CROs ”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of SLK for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA’ s or any other regulatory authority’ s GCPs or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger- scale facilities operated by a CMO and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us. ~~In addition, disruptions caused by the COVID- 19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.~~ We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen

safety issues or adverse side effects, failure to demonstrate a benefit from SLK, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of SLK beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of SLK, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. From time to time, we may publicly disclose preliminary data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We might also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of SLK and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, SLK may be harmed, which could harm our business, operating results, prospects or financial condition. Public health crises such as pandemics or..... this " Risk Factors " section. We face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. In particular, pharmaceutical companies that develop and / or market products for the indications we are pursuing, ~~namely~~ **including** HS and PsA, are likely to represent substantial competition. These include companies developing and / or marketing IL- 17A and IL- 17AA inhibitors (such as Novartis AG, Eli Lilly and Co, Amgen, Acelyrin, ~~DICE Therapeutics~~ **Zura Bio Ltd** and LEO Pharma), IL- 23 inhibitors (such as AbbVie, Janssen, Sun Pharmaceutical and Almirall), IL- 12 / 23 inhibitors (including Janssen), TNF alpha inhibitors (such as AbbVie, Pfizer, Janssen and UCB), TYK2 inhibitors (such as Bristol Myers Squibb), JAK inhibitors (such as AbbVie, Incyte and Pfizer), ~~MK2~~ **IL1a / IL1b inhibitors (including Abbvie), OX40L** inhibitors (such as **Sanofi** ~~Aclaris Therapeutics~~), and IRAK4 degraders (such as Kymera Therapeutics Inc). It also includes UCB as the development and commercializing company for **bimekizumab,** the only other IL- 17A and F inhibitor beyond SLK ~~(bimekizumab)~~ **that has received approval or is in late- stage clinical development** of which we are aware. While SLK represents a novel mechanism of action, all of the above mechanisms are also of potential therapeutic use in one or more ~~of the~~ **other** ~~two~~ indications **that we are** ~~being pursued now in the Phase 2 program~~ or **may be pursuing** ~~in axSpA or PsO~~ . If SLK does not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors. Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize SLK. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than SLK and these competitors may also be more successful than us in manufacturing and marketing their products. Furthermore, we also face competition more broadly across the market for existing cost- effective and reimbursable inflammatory skin and joint disease treatments. SLK, if approved, may compete with these existing drug and other therapies but may not be competitive with them in price. We expect that if SLK is approved, it will be priced at a significant premium over generic, including branded generic, or biosimilar products. **In particular, the availability of biosimilar products of adalimumab and in the future secukinumab may intensify competition.** As a result, obtaining market acceptance of, and gaining significant share of the market for, SLK will pose challenges. Patients in previous SLK trials have experienced adverse events, including oral Candida ~~. See the section titled " Business — Clinical Development of SLK "~~. If SLK is associated with undesirable side effects or has unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs, we may need to interrupt, delay or abandon SLK' s development or limit development to more narrow uses or subpopulations in which such potential undesirable side effects or other characteristics may be less prevalent, less severe or more acceptable from a risk- benefit perspective. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of SLK and may adversely affect our business, financial condition and prospects significantly. For details of the current understanding of the SLK safety profile, see the section entitled " Business ". Additionally, after SLK may receive marketing approval, we or others may later identify undesirable side effects or adverse events caused by SLK. In such cases, regulatory authorities may suspend, limit or withdraw approvals of SLK or seek an injunction against its manufacture or distribution, require additional warnings on the label, including " boxed " warnings, or issue safety alerts, require press releases or other communications containing warnings or other safety information about SLK, require us to change the way SLK is administered or conduct additional clinical trials or post-approval studies, require us to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients, impose fines, injunctions or criminal penalties. We could also be sued and held liable for harm caused to

patients, and our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of SLK, if approved, and could seriously harm **our business.Public health crises such as pandemics** ~~Future developments in these and other areas present material uncertainty and risk with respect to our~~ **or similar outbreaks could seriously and adversely affect our preclinical studies and ongoing and anticipated** clinical trials,business,financial condition and results of operations.As a result of ~~the COVID- 19 pandemic,or similar~~ pandemics ~~,~~ and related " shelter in place " orders and other public health guidance measures,we may in the future experience disruptions that could seriously harm our business.Potential disruptions include but are not limited to:delays or difficulties in enrolling patients in,initiating or expanding our clinical trials,including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;increased rates of patients withdrawing from our clinical trials following enrollment as a result of **certain** ~~contracting COVID- 19 or other~~ health conditions or being forced to quarantine;interruption of key clinical trial activities,such as clinical trial site data monitoring and efficacy,safety and translational data collection,processing and analyses,due to limitations on travel imposed;recommendations by federal,state or local governments,employers and others or interruptions of clinical trial subject visits,which may impact the collection and integrity of subject data and clinical trial endpoints;diversion of healthcare resources away from the conduct of clinical trials,including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;delays or disruptions in preclinical experiments and IND- enabling studies due to restrictions of on- site staff and unforeseen circumstances at CROs and vendors;interruption or delays in the operations of the FDA,EMA,and comparable foreign regulatory authorities including delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;interruption of,or delays in receiving,supplies of SLK from our CMOs due to staffing shortages,raw materials shortages,production slowdowns or stoppages and disruptions in delivery systems;and limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work,including because of sickness of employees or their families,the desire of employees to avoid travel or contact with large groups of people,an increased reliance on working from home,school closures or mass transit disruptions. **Future** ~~The COVID- 19 pandemic~~ **pandemics** may also affect the ability of the FDA,EMA,and other regulatory authorities to perform routine functions.If global health concerns prevent the FDA,EMA,or other regulatory authorities from conducting their regular inspections,reviews or other regulatory activities,it could significantly impact the ability of the FDA,EMA,or other regulatory authorities to timely review and process our regulatory submissions **,which could have a material adverse effect on** our business. Risks Related to Regulatory Process and Other Legal Compliance Matters The regulatory approval processes of the FDA, EMA, and other comparable foreign regulatory authorities are complex, time- consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for SLK, we may not be able to commercialize, or may be delayed in commercializing, SLK, and our ability to generate revenue will be materially impaired. The process of obtaining regulatory approvals in the United States, the EU, and other jurisdictions is complex, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize SLK in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize SLK outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of SLK, we must demonstrate through complex and expensive preclinical studies and clinical trials that SLK is both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Further, SLK may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA, EMA, and comparable foreign regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. SLK could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that SLK is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, or comparable foreign regulatory authorities for approval; serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to SLK; we may be unable to demonstrate that SLK' s clinical and other benefits outweigh its safety risks; the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of SLK may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA, EMA, or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and / or the specifications of SLK; the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Thus, the approval requirements for SLK are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere. Of the large number of drugs in development, only a small percentage successfully complete the FDA, EMA, or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market SLK, which would significantly harm our business, results of operations and prospects. If we were to obtain approval, regulatory authorities may approve SLK for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval

contingent on the performance of costly post- marketing clinical trials, or may approve SLK with a label that does not include the labeling claims necessary or desirable for the successful commercialization of SLK. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for SLK, we may not be able to commercialize, or may be delayed in commercializing, SLK and our ability to generate revenue could be materially impaired. We will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with SLK. Any regulatory approvals that we may receive for SLK will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of SLK, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. In addition, if the FDA, EMA, or comparable foreign regulatory authorities approve SLK, SLK and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA in the EU and comparable foreign regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA, and other regulatory authorities for compliance with cGMPs. If we or a regulatory authority discover previously unknown problems with SLK, such as adverse events of unanticipated severity or frequency, or problems with the facilities where SLK is manufactured, a regulatory authority may impose restrictions on SLK, the manufacturing facility or us, including requiring recall or withdrawal of SLK from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize SLK and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. The FDA' s, EMA' s and other regulatory comparable authorities' policies may change and additional government regulations may be enacted that could prevent, limit, delay, increase the cost or risks of obtaining regulatory approval of our product candidates, including if as a result new or more costly or difficult to achieve clinical trial or manufacturing quality requirements are imposed. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. Due to unfavorable pricing regulations and / or third- party coverage and reimbursement policies, we may not be able to offer SLK at competitive prices which would seriously harm our business. Our ability to successfully commercialize SLK also will depend in part on the extent to which reimbursement for SLK and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Failure to comply with the laws and regulations prohibiting the promotion of off-label uses can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The FDA, EMA, and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If SLK is approved and we are found to have improperly promoted off- label uses of SLK, we may become subject to significant liability. See the section titled " Business — Government Regulation ". If we cannot successfully manage the promotion of SLK, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We have adopted a code of conduct to more closely reflect our operations, but it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute SLK, if approved. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Healthcare providers, physicians and third- party payers play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third- party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain regulatory approval. See the section titled " Business — Government Regulation " for a more detailed description of the laws that may affect our ability to operate. Healthcare legislative reform discourse and potential or

enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business. Payers, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower- cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 % (increased to 70 % pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government' s comparative effectiveness research. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to amend or challenge the ACA, will impact our business. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration' s policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower- cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs the U. S. Department of Health and Human Services (" HHS ") to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA' s implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, the HHS' s CMS stated that drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for " best price " or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation (the " MFN ") Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development (" OECD ") countries with a similar gross domestic product per capita. However, the MFN rule was immediately challenged in federal courts and on August 6, 2021 CMS announced a proposed rule to rescind it. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. In response to litigation, the Biden administration agreed to delay the effective date of the rule until January 1, 2023. On November 15, 2021, Public Law 117- 58 went into effect. Section 90006 prohibits the Secretary of Health and Human Services from implementing the provisions of the final rule prior to January 1, 2026, extending the moratorium by an additional three years. Further, implementation of these changes and new safe harbors for point- of- sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. The effect of these legislative and executive activities on our business model and operations is currently unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and our external partners are subject to complex environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the rehabilitation of contaminated sites. Our operations,

including those performed by our external partners, may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we and / or our external partners may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We are subject to laws and regulations related to privacy, data protection, information security and consumer protection across different markets where we conduct our business. Our actual or perceived failure to comply with such obligations could harm our business. We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets ~~were~~ **where** we conduct our business. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any **data protection,** privacy laws or data security laws or any security incident or breach involving the potential or actual misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third party, could adversely affect our business, financial condition, and results of operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and / or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief. The collection and use of personal health data and other personal data in the EU is governed by the provisions of the GDPR, which ~~came~~ **became applicable** ~~into force~~ in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the ability to process (processing includes collecting, analyzing and transferring) personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation. In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the ~~EU /~~EEA that are not considered by the EC to provide an adequate level of data protection ~~(including the United States)~~ . Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the **EC' s** standard contractual clauses (“ SCCs ”). In this respect, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the ~~EU /~~EEA. For example, following the Schrems II decision of the Court of Justice of the EU on July 16, 2020, in which the Court invalidated the Privacy Shield under which personal data could be transferred from the ~~EU /~~EEA to United States entities who had self- certified under the Privacy Shield scheme, there is uncertainty as to the general permissibility of international data transfers under the GDPR. The Court did not invalidate the then- current SCCs, but ruled that data exporters relying on these SCCs are required to verify, on a case- by- case basis, if the law of the third country ensures **a** ~~an adequate~~ level of data protection that is essentially equivalent to that guaranteed in the ~~EU /~~EEA. In light of the implications of this decision, we may face difficulties regarding the transfer of personal data from the ~~EU /~~EEA to third countries. In 2021 the EC issued a new set of SCCs. Since December 27, 2022, ~~only~~ the **previous** ~~incorporation of the new~~ set of SCCs **can no longer be used** ~~ensures that the transfer is subject to appropriate safeguards~~ . When relying on SCCs, the data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and / or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. On June 18, 2021, the European Data Protection Board adopted recommendations to assist data exporters with such assessment and their duty to identify and implement supplementary measures where they are needed to ensure compliance with the EU level of protection to the personal data they transfer to third countries. **With regard to** ~~On March 25, 2022,~~ the ~~EC and~~ **transfer of personal data from the EEA to** the United States **,** ~~announced that they have agreed in principle~~ on ~~a new Trans~~ **July 10, 2023, the European Commission adopted its adequacy decision for the EU** - ~~Atlantic~~ **US** Data Privacy Framework. ~~Following this statement~~ **On the basis of the new adequacy decision** , **personal data** ~~President Biden signed an~~ **can flow from the EEA to** ~~Executive Order on ‘ Enhancing Safeguards for~~ United States **companies participating** ~~Signals Intelligence Activities’ on October 7, 2022. Along with the regulations issued by the Attorney General, the Executive Order implements into U. S. law the agreement~~ in ~~principle announced in March 2022. On that basis, the EC prepared a draft adequacy decision and launched its adoption procedure. While this new EU- US privacy framework is expected to enter into force in 2023, there~~ -- **the** ~~is still some uncertainty around the new~~ framework. In the event of a personal data breach, the GDPR also requires us, as a controller, to notify the competent supervisory authorities and / or the affected data subjects. Such notification must be issued without undue delay, **and** where feasible ~~,~~ not later than 72 hours after having become aware of the data breach. The notification obligation exists regardless of whether the processing is carried out on our or our vendors’ systems. The only exception where such notification may be omitted is if the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. In addition to the disruptions to our business and impact to our reputation that any such breach of security could cause, we may be subject to regulatory fines, class actions, or other costly measures if there is a personal data breach on our or our vendors’ systems. Furthermore, under the GDPR, when we act as a processor, we must notify the relevant controller without undue delay after become aware of a personal data breach. Failure to comply with the requirements of the GDPR and the related

national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to € 20 million or 4 % of the annual global ~~revenues~~ **turnover** of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both the EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised. Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU CTR, EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity that we face with regard to data protection regulation. With regard to the transfer of data from the EU to the United Kingdom **,** on June 28, 2021 ~~,~~ the EC adopted two adequacy decisions for the UK – one under the GDPR and the other for the Law Enforcement Directive. Personal data may now freely flow from the EU to the UK since the UK is deemed to have an adequate data protection level **for purposes of the EU regime** . However, the adequacy decisions include a ' sunset clause' which entails that the decisions will automatically expire four years after their entry into force **, unless renewed** . Additionally, following the UK' s withdrawal from the EU and the EEA, known as Brexit, companies also have to comply with the UK' s data protection laws (including the GDPR, as incorporated into UK national law), the latter regime having the ability to ~~separately~~ **impose** ~~fine~~ **fines** up to the greater of £ 17. 5 million or 4 % of global turnover. Furthermore, transfers from the UK to other countries, including the EEA, are subject to specific transfer rules under the UK regime **; personal data may freely flow from the UK to the EEA, since the EEA is deemed to have an adequate data protection level for purposes of the UK regime** . These UK **international** transfer rules broadly mirror the EU GDPR rules. **With regard to the transfer of personal data from the UK to the United States, from 12 October 2023, businesses in the UK can start to transfer personal data to US organizations certified to the " UK Extension to the EU- US Data Privacy Framework " (UK Extension) under the UK GDPR, without the need for further safeguards.** On March ~~25~~ **21** , 2022, the international data transfer agreement **(** ~~, or~~ IDTA ~~,~~ **) and** the international data transfer addendum to the EC' s standard contractual clauses for international data transfers **(** ~~, or~~ Addendum **)** , and a document setting out transitional provisions came into force and replaced the old EU SCCs **for purposes of the UK regime** . However, the transitional provisions, adopted with the IDTA and the Addendum, ~~allow the continued use, until March~~ **provide that contracts concluded on or before** 21 ~~,~~ **September** ~~2024~~ **2022** ~~,~~ **on the basis** of any **old** EU SCCs ~~, valid as at December 31,~~ **continue to provide appropriate safeguards for the purpose of the UK regime until 21 March** ~~2020~~ **2024** , ~~so long as~~ **provided that the processing operations that are the subject matter of** the contract ~~was entered into before September 21, 2022~~ **remain unchanged and appropriate safeguards can be ensured** . Furthermore, processing of personal data in Switzerland is governed by restrictive regulations, in particular with respect to health and medical data. The collection, storage, use, revision, disclosure, archiving or destruction of personal data in Switzerland is subject to the Federal Act on Data Protection (the " FDAP "); as well as various other federal and cantonal acts governing medical research and professional secrecy. This regulatory regime is going to be strongly adjusted by the ~~Revision~~ **revision** of the FDAP, which is coming into force on the September 1, 2023. The FDAP is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data and taking certain measures when engaging third- party processors. Compliance with the FDAP will be a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to sanctions. Breaches of or non- compliance with applicable data protection regulations and professional secrecy obligations could result in fines, or, under certain circumstances, imprisonment of the individuals responsible for the breach or non- compliance. The sanctions regime relating to data protection obligations will be more comprehensive under the revised FDAP. We cannot assure you that our third- party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and / or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third- party processing, use, storage, and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-

affiliated hospitals, universities, and other organizations. We also expect our non- U. S. activities to increase in time. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. The Cayman Islands Economic Substance Act may affect our operations. The Cayman Islands has recently enacted the International Tax Co- operation (Economic Substance) Act (As Revised) (the " Cayman Economic Substance Act "). The Cayman Economic Substance Act generally requires legal entities domiciled or registered in the Cayman Islands and carrying out specific " relevant activities " to have demonstrable substance in the Cayman Islands. The Cayman Economic Substance Act was introduced by the Cayman Islands to ensure that it meets its commitments to the EU, as well as its obligations under the OECD' s global Base Erosion and Profit Shifting initiatives. We are required to comply with the Cayman Economic Substance Act. As we are a Cayman Islands company, compliance obligations include filing annual notifications for the Company, which need to state whether the Company is carrying out any relevant activities and, if so, whether we have satisfied economic substance tests to the extent required under the Cayman Economic Substance Act. As it is a relatively new regime, it is anticipated that the Cayman Economic Substance Act will evolve and be subject to further clarification and amendments. We may need to allocate additional resources to keep updated with these developments, and may have to make changes to our operations in order to comply with all requirements under the Cayman Economic Substance Act. Failure to satisfy these requirements may subject us to penalties under the Cayman Economic Substance Act. The Cayman Islands Tax Information Authority shall impose a penalty of CI $ 10, 000 (or US $ 12, 500) on a relevant entity for failing to satisfy the economic substance test or CI $ 100, 000 (or US $ 125, 000) if it is not satisfied in the subsequent financial year after the initial notice of failure. Following failure after two consecutive years the Grand Court of the Cayman Islands may make an order requiring the relevant entity to take specified action to satisfy the economic substance test or ordering it that it is defunct or be struck off. Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain. Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed drug products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our drug candidate, if approved for commercial use, or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the IRA, which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business We are dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain qualified managerial, scientific and medical personnel. We are dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, our Chief Scientific Officer, and our Chief Financial Officer. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts. Furthermore, we are dependent on our ability to attract, hire, relocate and retain qualified managerial, scientific and medical personnel from jurisdictions other than Switzerland ~~and ,~~ the United Kingdom **and Portugal** . Therefore, Swiss ~~and ,~~ British **and Portuguese** immigration requirements have a significant influence on our human resources planning. Immigration applications can take several months or more to be finalized. If we are unable to complete the requisite visa applications, either as a result of changing requirements or otherwise, our ability to successfully implement our business strategy could suffer, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical operations, regulatory affairs and, potentially, others. To manage our anticipated future growth, we must continue to implement and develop our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to ~~our limited financial resources and~~ the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel **. Failure in our information technology and storage systems or those of third parties upon whom we rely could significantly disrupt the operation of our business and adversely impact our financial condition. Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology (" IT ") systems or those of third parties upon whom we rely. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters (such as a tornado, an earthquake, or a fire). Moreover, despite network security and back- up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break- ins, including cyber- attacks, computer viruses, and similar disruptive problems. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently, and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate**

preventative measures. If the IT systems are compromised, we could be subject to fines, damages, litigation, and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. Despite precautionary measures designed to prevent unanticipated problems that could affect the IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. In addition, the failure of our systems, maintenance problems, upgrading or transitioning to new platforms, or a breach in security could result in delays and reduce efficiency in our operations. Remediation of such problems could result in significant, unplanned capital investments. Furthermore, parties in our supply chain may be operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen, and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business . Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations. Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third- party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and / or other third parties, or from cyber- attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. **In addition, techniques used to obtain unauthorized access to networks in which data is stored or through which data is transmitted change frequently and generally are not recognized until launched against a target. As a result, we may be unable to anticipate these techniques or implement adequate preventative measures to prevent such an event.** To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of SLK could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored **. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that any existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third- party service providers to comply with our data privacy, security, protection, or confidentiality, or to respond to any data security incidents, breaches or other unauthorized access, acquisition, or disclosure of sensitive information (including, without limitation personal information), may result in additional cost and / or liability to us, including costs from governmental investigations, enforcement actions, regulatory fines, litigation, costs of doing business, or damage to our reputation. Any of these events could cause harm to our reputation, business, financial condition, or operational results** . Risks Related to Reliance on Third Parties We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize SLK. We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third- party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations, even if responsibilities have been outlined in agreements with external partners, such as CROs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to SLK. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance

on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize SLK. We do not currently own or operate any facility that may be used to produce SLK (including any drug substance or finished drug product) and must currently rely on CMOs to produce them for us. We have not yet caused SLK to be manufactured ~~on~~ **in** a ~~commercial~~ **commercially** ~~scale~~ **validated and registered process** and may not be able to do so ~~for SLK, if approved~~ . We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of SLK. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA, or a comparable foreign regulatory authority does not approve these facilities for the manufacture of SLK or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market SLK, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of SLK, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of SLK and harm our business and results of operations. Moreover, if any CMOs on which we will rely fail to manufacture quantities of SLK at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. Our business could be similarly affected by business disruptions to our third- party providers with potential impacts on our future revenue and financial condition and our costs and expenses. Each of these risks could delay or prevent the completion of our clinical trials or the approval of SLK by the FDA, result in higher costs or adversely impact commercialization of SLK. **Moreover, we have not yet completed the development of the autoinjector device for SLK and may not be able to do.** We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements. We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to SLK and / or our Company more broadly. Any of these relationships may require us to increase our near and long- term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business. Risks Related to Our Intellectual Property We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to SLK and our technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection for SLK and its uses, components, formulations, methods of manufacturing and methods of treatment, as well as our ability to operate without infringing on or violating the proprietary rights of others. We own and have licensed rights to patent applications and pending patent applications, and expect to continue to file patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent. We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world. We may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on SLK worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. We have licensed patents in the most relevant countries but may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of SLK or its intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Further, even if these patents are granted, they may be difficult to enforce. In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other

requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office (" USPTO ") and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non- compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, and non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved. Issued patents covering one or more of our drug candidates could be found invalid or unenforceable. Any issued patents that we may license or own covering SLK could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position with respect to SLK for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, enforceability of our patents and / or other intellectual property. Finally, changes in U. S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect SLK. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market SLK under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage. Moreover, we or our licensors may be subject to a third- party pre- issuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or SLK and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize SLK. In addition to seeking patents for some of our technology and SLK, we may also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third- party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. **As our organization grows, so does the risk of unauthorized disclosure of confidential information.** We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect ~~its~~ **our** trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A Ordinary Shares. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to ~~sustain~~ **absorb** the costs of such litigation or proceedings more effectively than we can. Uncertainties resulting from the initiation and

continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. Patent terms may be inadequate to protect our competitive position with respect to SLK for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering SLK are obtained, once the patent life has expired, we may be subject to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for SLK, our business may be materially harmed. In the United States, the patent term of a patent that covers an FDA- approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in the EU and certain other non- United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when SLK receives FDA approval, we expect to apply for patent term extensions on patents covering SLK, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed. It is possible that we will not succeed in obtaining patent term extension under the Hatch- Waxman Act for a U. S. patent covering SLK that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch- Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO. Also, we may be unable to obtain patents covering SLK that contain one or more claims that satisfy the requirements for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If SLK is approved and a patent covering SLK is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of SLK. Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect SLK. Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") could increase the uncertainties and costs surrounding the prosecution of our owned and in- licensed patent applications and the maintenance, enforcement or defense of our owned and in- licensed issued patents. The Leahy- Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost- effective avenues for competitors to challenge the validity of patents, and enable third- party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent at USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Also, under the Leahy- Smith Act, the United States transitioned **from a first- to- invent** to a first- to- file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention **. Foreign counterparts to this law are also not uniform, and there is no worldwide policy governing the subject matter and scope of claims granted in a pharmaceutical or biotechnology patent** . As such, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and altered the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future legislation by the U. S. Congress, decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material

adverse effect on our business and financial condition. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market SLK. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of SLK in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market SLK. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering SLK or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing SLK or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing SLK. Because the intellectual property landscape in the biotechnology industry is rapidly evolving and is interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on or violating third party rights. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon SLK and / or seek a license from the patent holder. In addition, any intellectual property claims (e. g. patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to ~~sustain~~ **absorb** the costs of complex intellectual property litigation more effectively than we can. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of our Class A Ordinary Shares. Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time- consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. Further, we may be required to protect our patents through procedures created to challenge the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition, if SLK is found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay

damages on behalf of those parties or may be required to obtain a license for SLK. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. We license patent rights from third- party owners and thus our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others. We are a party to certain licenses, including with our licensor with MHKDG, that provide us rights to intellectual property that are necessary or useful for SLK and its respective components, formulations, methods of manufacturing and methods of treatment. These license agreements require us to satisfy certain obligations and, if these agreements are terminated (e. g., as a result of our failure to satisfy such obligations), our technology and our business could be adversely affected. We may also enter into additional licenses to third- party intellectual property in the future; however, we may not be able to obtain such licenses on economically feasible terms or other reasonable terms and conditions, or at all. Additionally, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In those instances, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. If we, or our licensors, are not able to obtain and maintain patent protection for any products that we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or substantially identical to ours, which could adversely affect our competitive business position and harm our business prospects. Even if patents are issued in respect of these patent applications, we or our licensors may determine not to pursue litigation against other companies that are infringing these patents, or may not be able to pursue such litigation at a reasonable cost or in a timely manner. Our license from MHKDG may be subject to retained rights. MHKDG retains certain rights under its license agreement with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether MHKDG limits its use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. We may not be able to effectively secure first- tier technologies when competing against other companies or investors. Our future success may require that we acquire patent rights and know- how to new or complimentary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and / or technologies. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights. The degree of future protection afforded by our intellectual property rights, whether owned or in- licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include: • pending patent applications that we own or license may not lead to issued patents; • patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable; • others may be able to develop and / or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in- licensed patents, should any such patents issue; • third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection; • we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license; • we (or our licensors) might not have been the first to file patent applications covering a particular invention; • others may independently develop similar or alternative technologies without infringing our intellectual property rights; • we may not be able to obtain and / or maintain necessary licenses on reasonable terms or at all; • **we may develop patents that could expire prior to or shortly after commencing commercialization of a product; •** third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property; • we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; • we may not develop or in- license additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business and results of operation. If approved, our product candidates that are regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway. The Biologics Price Competition and Innovation Act of 2009 ~~,~~ ~~or~~ **(the "** BPCIA **")** , was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was

first licensed. During this 12- year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not reply on the reference product, sponsor' s data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products. We believe that SLK approved in the United States as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure. Risks Related to Our Class A Ordinary Shares The price of our shares may be volatile, and you could lose all or part of your investment. The trading price of our Class A Ordinary Shares is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K. The realization of any of these factors could have an adverse impact on the market price of our Class A Ordinary Shares. In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In ~~particular, the trading prices for biotechnology companies have been volatile as a result of the COVID- 19 pandemic. In~~ addition, broad market and industry factors may negatively affect the market price of our Class A Ordinary Shares, regardless of our actual operating performance. The market price for our Class A Ordinary Shares may be influenced by many factors, including: • the success of competitive products or technologies; • advancement of our preclinical programs into clinical testing; • results of clinical trials of our product candidates or those of our competitors; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our programs and product candidates or preclinical and clinical development programs; • the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. If our share price is volatile, we may be subject to securities litigation, which is expensive and could divert management attention. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would materially adversely affect our business, financial condition and results of operation. Sales of our Class A Ordinary Shares, or the perception that such sales may occur, may cause the market price of the Class A Ordinary Shares to decline significantly, even if our business is doing well. ~~Certain holders of shares of our common stock are subject to lock- up periods. Following the expiration of such lock- up periods, sales~~ **Sales** ~~of a substantial number of Class A Ordinary Shares in the public market could occur. These sales~~ , or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Class A Ordinary Shares. As restrictions on resale end and registration statements (filed to provide for the resale of such shares from time to time) are available for use, the sale or possibility of sale of these shares could have the effect of increasing the volatility in our share price or the market price of the Class A Ordinary Shares could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them. Our principal shareholders and management own a significant percentage of our stock and are able to exert significant influence over matters subject to shareholder approval. As of December 31, ~~2022~~ **2023** , our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially own a significant portion of our outstanding voting common stock. These shareholders, acting together, may be able to impact matters requiring shareholder approval. They may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may feel are in your best interest as one of our shareholders. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their shares, and might affect the prevailing market price for our Class A Ordinary Shares. Anti- takeover provisions in our organizational documents could delay or prevent a change of control. Certain provisions of our Memorandum and Articles of Association (the" MAA") and Cayman Islands Law may have an anti- takeover effect and may delay, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a shareholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares held by our members. These provisions provide for, among other things: • establishing a classified Board; • allowing the Board to issue one or more series of preference shares; • establishing advance notice for nominations of directors by members and for members to include matters to be considered at general meetings; • eliminating the ability of members to fill vacancies on the Board; • establishing advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon by at our annual general meetings; • permitting the Board to establish the number of directors; • eliminating the ability of members to call general meetings or act by written consent; • requiring a special resolution to amend the MAA; and • limit the jurisdictions in which certain shareholder litigation may be brought. These anti- takeover provisions could make it more

difficult for a third party to acquire our Company, even if the third party' s offer may be considered beneficial by many of our shareholders. As a result, our shareholders may be limited in their ability to obtain a premium for their shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors of your choosing and to cause us to take other corporate actions you desire. Our indemnification obligations to our officers and directors may result in a significant cost to us and hurt the interests of our shareholders. Cayman Islands law does not limit the extent to which a company' s memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against willful default, willful neglect, actual fraud or the consequences of committing a crime. The MAA provides for indemnification of our officers and directors to the maximum extent permitted by law, including for any liability incurred in their capacities as such, except through their own actual fraud, willful default or willful neglect. We purchased a policy of directors' and officers' liability insurance that insures our officers and directors against the cost of defense, settlement or payment of a judgment in some circumstances and insures us against our obligations to indemnify our officers and directors. We have entered into indemnification agreements with each of our directors and executive officers that obligate us to indemnify, hold harmless, exonerate, and to advance expenses as incurred, to the fullest extent permitted under applicable law, from damage arising from the fact that such person is or was an officer or director of our Company or its subsidiaries. Our indemnification obligations may discourage shareholders from bringing a lawsuit against our officers or directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our officers and directors, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder' s investment may be adversely affected to the extent we pay the costs of settlement and damage awards against our officers and directors pursuant to these indemnification provisions. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on its capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our Class A Ordinary Shares will be your sole source of gain for the foreseeable future. Future issuances of debt securities and equity securities may adversely affect our Company, including the market price of our Class A Ordinary Shares and may be dilutive to existing shareholders. There is no assurance that we will not incur debt or issue equity ranking senior to the Class A Ordinary Shares. Those securities will generally have priority upon liquidation. Such securities also may be governed by an indenture or other instrument containing covenants restricting its operating flexibility. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences and privileges more favorable than those of Class A Ordinary Shares. Separately, additional financing may not be available on favorable terms, or at all. Because our decision to issue debt or equity in the future will depend on market conditions and other factors beyond our control, it cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts. As a result, future capital raising efforts may reduce the market price of Class A Ordinary Shares and be dilutive to existing shareholders. General Risk Factors ~~We are an " emerging growth company " and it cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the Class A Ordinary Shares less attractive to investors. We are an " emerging growth company " as defined in the JOBS Act. As an emerging growth company, we are only required to provide two years of audited financial statements and management discussion and analysis of financial condition and results of operations disclosure. In addition, we are not required to obtain auditor attestation of reporting on internal control over financial reporting, have reduced disclosure obligations regarding executive compensation and are not required to hold non- binding advisory votes on executive compensation. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. These provisions allow an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of such extended transition period. We cannot predict whether investors will find the Class A Ordinary Shares to be less attractive as a result of its reliance on these exemptions. If some investors find the Class A Ordinary Shares to be less attractive as a result, there may be a less active trading market for the Class A Ordinary Shares and the price of the Class A Ordinary Shares may be more volatile than the current trading market and price of Class A Ordinary Shares. We will remain an emerging growth company until the earliest of: (i) the end of the fiscal year in which we have total annual gross revenue of $ 1. 235 billion; (ii) December 31, 2025; (iii) the date on which we issue more than $ 1. 0 billion in non- convertible debt during the preceding three- year period; or (iv) the end of the fiscal year in which the market value of the Class A Ordinary Shares held by non- affiliates exceeds $ 700 million as of the last business day of our most recently completed second fiscal quarter. Further, there is no guarantee that the exemptions available under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, it will incur additional compliance costs, which may impact our financial condition.~~ We may become a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we would be exempt from certain provisions applicable to U. S. domestic public companies. We may become a " foreign private issuer " as defined in Rule 36- 4 promulgated under the Exchange Act. If we do become a foreign private issuer, we would be exempt from certain rules and regulations in the United States that are applicable to U. S. domestic issuers, including: • the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10- Q or current report on Form 8- K; • the section of the Exchange Act regulating the solicitation of proxies, consents or authorizations respect of a security registered under the Exchange Act; • the section of the Exchange Act requiring directors, officers and 10 % holders to file public reporting of their stock ownership and trading activities and imposing liability on insiders who profit from trades made in a short period of time; and • the selective disclosure rules under Regulation FD restricting issuers from selectively disclosing material nonpublic information. Accordingly, the information we would be required to file with or furnish to the SEC as a foreign private issuer is less extensive and less frequent as compared to the

information required to be filed with the SEC by U. S. domestic issuers. In addition, if we become a foreign private issuer whose securities are listed on Nasdaq, we would permitted to, and may elect to, follow certain home country corporate governance practices in lieu of the requirements of the Nasdaq Rules pursuant to Nasdaq Rule 5615 (a) (3). Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards applicable to U. S. domestic issuers and may afford our shareholders less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards applicable to U. S. domestic issuers. We would be required to disclose any significant ways in which our corporate governance practices differ from those followed by U. S. domestic issuers under Nasdaq corporate governance listing standards in an annual report on Form 20- F filed with the SEC or on our website.